

10-04-05

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PTO/SB/21 (09-04)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/964,273
	Filing Date	September 26, 2001
	First Named Inventor	Sean Brynjelsen
	Art Unit	1615
	Examiner Name	P. A. Hawes
Total Number of Pages in This Submission	Attorney Docket Number	CPIFT-5776 (3360-0004)

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): - Forms PTO/SB/08A and /08B - Check # 21693 for \$180 - 37 cited references - Certificate of Mailing - Return Postcard
<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Cook, Alex, McFarron, Manzo, Cummings & Mehler, Ltd.		
Signature			
Printed name	Raymond M. Mehler		
Date	October 3, 2005	Reg. No.	26,306

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name	Barbara Gesiakowski	Date	October 3, 2005

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PATENT  
Attorney Docket No. CPIFT-5776 (3360-0004)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of: )

Brynjelsen et al. )

Serial No.: 09/964,273 )

Filed: September 26, 2001 )

Group Art No.: 1615 )

Examiner: P. A. Hawes )

For: PREPARATION OF SUBMICRON )  
SOLID PARTICLE SUSPENSIONS )  
BY SONICATION OF MULTIPHASE )  
SYSTEMS )

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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NAME Barbara Gesiakowski

SIGNATURE B. Gesiakowski

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1. Transmittal Form PTO/SB/21 (1 sheet);
2. Information Disclosure Statement (3 sheets);
3. Fee Transmittal for FY 2005 in duplicate;
4. Check #21693 for \$180.00;
3. Foreign Patent Documents and Non-Patent Publications (37 Documents);
4. PTO/SB/08A and /08B (4 sheets);
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Name: Barbara Gesiakowski

Signature: B. Gesiakowski



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Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL for FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

## Complete If Known

Application Number	09/964,273
Filing Date	September 26, 2001
First Named Inventor	Sean Brynjelsen
Examiner Name	P. A. Hawes
Art Unit	1615
Attorney Docket No.	CPIFT-5776 (3360-0004)

TOTAL AMOUNT OF PAYMENT (\$180.00)

## METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 50-1039 Deposit Account Name: Cook, Alex, McFarron, Manzo, et al.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee  
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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## FEE CALCULATION

### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

### 2. EXCESS CLAIM FEES

Fee Description	Small Entity		
	Fee (\$)	Fee (\$)	
Each claim over 20 (including Reissues)	50	25	
Each independent claim over 3 (including Reissues)	200	100	
Multiple dependent claims	360	180	
<b>Total Claims</b>			
- 20 or HP = _____ x _____ = _____			
HP = highest number of total claims paid for, if greater than 20			
<b>Indep. Claims</b>			
- 3 or HP = _____ x _____ = _____			
HP = highest number of independent claims paid for, if greater than 3			

### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

**Total Sheets** - 100 = **Extra Sheets** /50= **Number of each additional 50 or fraction thereof** (round up to a whole number) x **Fee (\$)** = **Fee Paid (\$)**

### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Supplemental Information Disclosure Statement Fee 180.00

### SUBMITTED BY

Signature		Registration No. 26,306 (Attorney/Agent)	Telephone 312-236-8500
Name (Print/Type)	Raymond M. Mehler		Date October 3, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT  
Attorney Docket No. CPIFT-5776 (3360-0004)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: )  
Sean Brynjelsen et al. )  
Serial No.: 09/964,273 )  
Filed: September 26, 2001 )  
Examiner: P. A. Hawes )  
Art Unit: 1615 )  
For: PREPARATION OF SUBMICRON )  
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NAME <u>Barbara Gesiakowski</u> (TYPED OR PRINTED)
SIGNATURE: <u>B. Gesiakowski</u>

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.97, Applicants hereby call the Examiner's attention to documents listed on the attached forms, which documents may be material to the examination of this application. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

10/06/2005 HLE333 00000023 09964273

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Copies of the U.S. patents and U.S. patent publications are not enclosed pursuant to the Office's waiving of the requirement under 37 C.F.R. §1.98, paragraph (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication.

No inference should be drawn that any apparatus or method disclosed is equivalent to the subject invention. Also, the citation of the above-discussed documents is not to be construed as an assertion that more pertinent art could not possibly be in existence. Citation of any document herein is not to be construed as an admission that any subject matter disclosed in the document is necessarily within the inventive field of endeavor, that any disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that any disclosure is otherwise necessarily prior art with respect to the instant invention.

Applicants also respectfully reserve the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosure of those documents discussed herein, that may be cited by the Examiner in rejecting a claim in the present patent application.

This Information Disclosure Statement is being submitted after the mailing date of a first Office Action on the merits but before a final action or an action that closes prosecution under 37 C.F.R. § 1.97(c)(2). Consequently, a fee under §1.17(p) is required for the filing of this information disclosure, and is enclosed. If it is determined that an additional fee is required, then authorization is hereby granted to charge Deposit Account 50-1039 any additional fee required.

(A duplicate of this document is enclosed herewith.)

Respectfully submitted,

Date: October 3, 2005

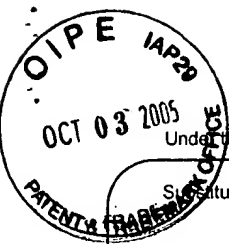
By: 

Raymond M. Mehler, Esq.  
Registration No. 26,306  
Cook, Alex, McFarron, Manzo,  
Cummings & Mehler, Ltd.  
200 West Adams St., Suite 2850  
Chicago, IL 60606  
Telephone: (312) 236-8500  
Attorneys for Applicant









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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	09/964,273
Filing Date	September 26, 2001
First Named Inventor	Sean Brynjelsen
Art Unit	1615
Examiner Name	P. A. Hawes
Attorney Docket Number	CPIFT-5776 (3360-0004)

Sheet

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of

4

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	32	Kinman et al., "Lipid-Drug Association Enhanced HIV-1 Protease Inhibitor Indinavir Localization in Lymphoid Tissues and Viral Load Reduction: A Proof of Concept Study in HIV-2 <sub>87</sub> -Infected Macaques", Journal of Acquired Immune Deficiency Syndrome, 34(4), pp. 387-397	
	33	Limoges et al., poster presentation, 11th Conference on Retroviruses and Opportunistic Infections, February 8-11, 2004.	
	34	Moghimi et al., "Long-Circulating and Target-Specific Nanoparticles: Theory to Practice", Pharmacological Reviews, 53, pp. 283-318, 2001.	
	35	Nesbit et al., "In Vitro and Animal Models of Human Immunodeficiency Virus Infection of the Central Nervous System", Clinical and Diagnostic Laboratory Immunology, 9(3), pp. 515-524, May 2002.	
	36	Nottet et al., "HIV-1 Entry into Brain: Mechanisms for the Infiltration of HIV-1 infected Macrophages Across the Blood-Brain Barrier", The Neurology of AIDS, p. 55, 1998.	
	37	Perno et al., "Relative Potency of Protease Inhibitors in Monocytes/Macrophages Acutely and Chronically Infected with Human Immunodeficiency Virus", The Journal of Infectious Diseases, 178, pp. 413-422, 1998.	
	38	Sawchuk et al., "Investigation of distribution, transport and uptake of an anti-HIV drugs to the central nervous system", Advanced Drug Delivery Reviews, 39, pp. 5-31, 1999.	
	39	Solas et al., "Discrepancies between Protease Inhibitor Concentrations and Viral Load in Reservoirs and Sanctuary Sites in Human Immunodeficiency Virus-Infected Patients", Antimicrobiology Agents and Chemotherapy, 47 (1), pp. 238-243, January 2003.	
	40	Shrayer, et al., "Ceramide, a mediator of apoptosis, synergizes with paclitaxel to induce regression of the L 3.6 human pancreatic carcinoma implanted in SCD1 mice", Journal of Clinical Oncology, Vol. 22, No. 14S, Abstract, 2004:2135.	
	41	Schroeder et al., "Distribution of Radiolabeled Subvisible Microspheres after Intravenous Administration to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol. 67, No. 4, pp. 504-507, April 1978.	

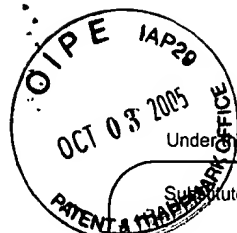
Examiner Signature	Date Considered
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Sheet

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	42	Allen et al., "Large unilamellar liposomes with low uptake into the reticuloendothelial system", FEB, Vol. 223, No. 1, pp. 42-46, 1987.	
	43	Allen et al., "Effects on the murine mononuclear phagocyte system of chronic administration of liposomes containing drug or lipid A compared with empty liposomes", Can. J. Physiol. Pharmacol., Vol. 65, pp. 185-190, 1987.	
	44	Graham, D.T., et al., "The Effects of Freezing on Commercial Insulin Suspensions", International Journal of Pharmaceutics, pp. 315-322, 1978.	
	45	Bender et al., "Efficiency of Nanoparticles as a Carrier for Antiviral Agents in Human Immunodeficiency Virus-Infected Human Monocytes/Macrophages In Vitro", Antimicrobial Agents and Chemotherapy, 40(6), pp. 1467-1471, June 1996.	
	46	H. von Briesen, "Controlled Release of Antiretroviral Drugs", AIDS Rev., 2, pp. 31-38, 2000.	
	47	Aquaro, et al., "Macrophages and HIV infection: therapeutic approaches toward this strategic virus reservoir", Antiviral Research 55, pp. 209-225, 2002.	
	48	Crowe, et al., "The contribution of monocyte infection and trafficking to viral persistence, and maintenance of the viral reservoir in HIV infection", Journal of Leukocyte Biology, Vol. 74, pp. 635-641, November 2003.	
	49	Fischer-Smith et al., CNS invasion by CD14+/CD16+ peripheral blood-derived monocytes in HIV dementia: perivascular accumulation and reservoir of HIV infection", Journal of NeuroVirology, 7, pp. 528-541, 2001.	
	50	Igarashi et al., "Macrophage are the principal reservoir and sustain high virus loads in rhesus macaques after the depletion of CD4+ T cells by a highly pathogenic simian immunodeficiency virus/HIV type 1 chimera (SHIV): Implications for HIV-1 infections of humans", PNAS, 98(2), pp. 658-663, January 16, 2001.	

Examiner  
SignatureDate  
Considered

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